

## **REMARKS/ARGUMENTS**

This communication responds to the Office Action of June 1, 2009, in which claims 1-33, 35, and 36 are pending. Claims 1, 14, 24, and 32 are independent claims.

With this Response and Amendment, claims 1, 6, 24, and 32 are currently amended, and claim 37 is new. Support for new claim 37 can be found in the claims as filed and throughout the Specification, for example at paragraphs [0036]-[0043]. Accordingly, after entry of this Response and Amendment, claims 1-33 and 35-37 are pending and under examination in the application.

Applicants have not publicly dedicated or abandoned any unclaimed subject matter, and have not acquiesced to any rejections made by the Office in the Office action. Applicants reserve the right to pursue prosecution of any presently or previously excluded or cancelled claim embodiments in one or more future continuation and/or divisional applications.

### **I. Request for Interview**

Applicants expressly request an interview with the Examiner to discuss allowance of claims and/or narrowing amendments in advance of an additional office action that would put the claims in condition for allowance.

Applicants note that any new grounds for rejection, particularly related to unamended claim 14, are not necessitated by amendment, and thus require a non-final office action.

### **II. Claim Objections**

The Examiner has objected to claim 1 arguing that “the donor bone parameters’ . . . lacks antecedent basis.” While Applicants argue that “the donor bone” does not lack an antecedent, claim 1 is currently amended to recite “measuring parameters of the donor bone,” making explicit that which was previously inherent.

The Examiner states that claim 6 does not have a period at the end of the sentence. Claim 6 is currently amended to include a period.

The Examiner objects to claims 7, 30 and 31 under 37 C.F.R. §1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. 37 C.F.R. §1.75(c) states, “[o]ne or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application.” For at least the following reasons, each of claims 7, 30, and 31 “further limit[ ] another claim,” and should be allowed in their current form. Each claim is addressed in turn below.

Claim 7 depends from claim 6, which in turn depends from claim 4. Claim 4 recites “formulating an implant cutting plan” in part “based on the measured parameters” of independent claim 1. Claim 6 recites that the “cutting plan” of claim 4 “is formulated from a computer based model.” Claim 7 recites that “the model” of claim 6 is “scalable.” Thus, claim 7 does not “fail to provide a further step to the process of parent claim[ ] 1,” rather claim 7 is a “scalable” “computer based model.” Therefore, claim 7 further limits claims 6 and 7.

Claim 30 depends from claim 1, and recites that the process of claim 1 “is employed as a method for determining critical attributes of bone related to predetermined release specifications,” and that these critical attributes may be used in “either processing or final product specification.” Therefore, claim 31 further limits claim 1 and does not “fail to provide a further step to the process of parent claim[ ] 1” as argued by the Examiner.

Claim 31 recites that the process of independent claim 14 is further “employed as a method for determining critical attributes of bone related to predetermined release specifications,” and that these critical attributes may be used in “either processing or final product specification.” Therefore, claim 31 further limits claim 1 and does not “fail to provide a further step to the process of parent claim[ ] 1” as argued by the Examiner.

### **III. Claim Rejections Under 35 U.S.C. §101**

The Examiner rejects claims 24-29, 32-33, 35 and 36 under 35 U.S.C. § 101 arguing that “these are method or process claims that do not transform underlying subject matter . . . to a different state or thing, nor are they tied to a particular machine.” The Federal Circuit, in *In re Bilski*, has held that method claims must satisfy a “machine or transformation test.” 545 F.3d 943, (Fed. Cir. 2008). The court reaffirmed the Supreme Courts test that the claimed process must: (1) be

tied to a particular machine or apparatus (machine implemented); or (2) particularly transform a particular article into a different state or thing.” Id. citing to *Gottschalk v. Benson*, 409 U.S. 63 (1972). The Federal Circuit, in *Bilski*, examined a claim involving computed tomography of bone, and made explicit that the transformation need not be of a physical object, but may transform data representing a physical object:

“We further note for clarity that the electronic transformation of the data itself into a visual depiction in Abele was sufficient; the claim was not required to involve any transformation of the underlying physical object that the data represented.  
*Bilski*. at 26.

Independent claims 24 and 32 as written, transform a physical object into data, and further transform that data representing the physical object into an either an assessment (claim 24) or a cutting plan (claim 32). Without acquiescing to the Examiner’s rejection, and in the interest of expediting prosecution, the Applicants have also amended claims 24 and 32 to make recite “storing or writing the assessed cortical thickness in computer memory,” and “said cutting plan is stored in computer memory or used to generate a work order,” respectively. The claims therefore transform data representing a physical object as required by *Bilski*.

For at least these reasons, the Examiner’s rejection of claims 24-29, 32-33, 35 and 36 under 35 U.S.C. § 101 fails and should be withdrawn.

#### **IV. Claim Rejections Under 35 U.S.C. §103**

Claims 1-8, 10-18, 20-33, 35 and 36 were rejected under 35 U.S.C. § 103(a) as unpatentable over Morris et al. (US 6,458,144) in view of Dore et al. (US 2003/0236473).

As made explicit in the M.P.E.P., a proper obviousness rejection based on a rationale of combining elements found in separate references requires at least a finding that the cited references teach the claimed elements and that the only difference between the elements of the references and the claim “being the lack of actual combination of the elements.” MPEP § 2143(A). See also *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974); *CFMT, Inc. v. YieldUp Int’l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).

**A. Morris in light of Dore do not teach the present method of independent claims 1, 14, 24, 32, or newly presented claim 37.**

Morris does not teach the presently claimed method. Rather, Morris describes a technique for measuring bone implants for suitability after they have been produced from a bone rather than before so as to determine the bone's suitability for fabrication into an implant. Morris does not teach "using a three-dimensional imaging scan . . . of the bone." Instead, Morris inspects the dowel implants after their removal from the bone. There is no imaging, or even inspection for "assessing the donor bone's suitability for fabrication into a given implant configuration," as is currently required by claim 1. Morris describes that "[a] bone shaft 14 is selected for producing the threaded cortical dowels," but rather than teaching that the bone shaft is imaged to so that bone parameters may be measured, Morris simply suggests the use of "the shaft of a femur, ulna, radius, tibia or fibula." Measuring of the donor bone parameters is not attempted until the dowel "may be removed from dowel cutter 24 by hand or by the use of air." It is not until after removal of the dowel that Morris teaches performing a "check of the sidewall thickness of bone dowel 46 . . . to determine the adequacy thereof." Additionally, this check is only completed after the "[b]one dowel 46 is rinsed in water to remove loose bone particles from its exterior and medullary canal 18."

Neither Ateshian nor Dore compensate for the failings of Morris. Dore is directed at "modeling a body part with a high precision . . . to create a replica of the body part or an implant tightly fitting the said body part." Ateshian is directed to "[a] joint prosthesis for attachment to a bone of a patient," Neither Ateshian nor Dore teach the currently claimed methods described in independent claims 1, 14, 24, or 32.

Thus, Ateshian, Dore, and Morris fail to support a prima facie case of obviousness regarding any of the currently claimed methods.

Independent claims 14, 24, and 32 are not specifically argued by the Examiner. Thus it is unclear where in Morris, Dore, or Ateshian these claims are taught. However, among other failings including those detailed above, the references do not teach: "extrapolating from morphometric measurements to dimensions at another skeletal site on the same or another bone," as required by claim 14; or "non-destructively assessing cortical thickness at one or more pre-

selected sites of the donor bone,” as required in claim 24; or “formulating a bone implant cutting plan” and “measurements specify data regarding the fabrication of a given implant configuration for the donor bone,” as required in claim 32.

**V. The references cited by the examiner neither anticipate nor obviate new claim 37.**

Current claim 37 recites:

“[a] method for processing donor bone for implantation comprising: a. imaging a donor bone, prior to implantation, using a three-dimensional imaging scan at one or more sites of the bone; b. measuring parameters of the donor bone from the scan image; c. assessing the donor bone’s suitability for fabrication into a given implant configuration based on the measured parameters; d. formulating an implant cutting plan; and e. using a computer assisted device to cut the donor bone into multiple implants based on the implant cutting plan.

Neither Ateshian, Dore, nor Morris individually or in combination recite aspects of the presently claimed method for processing donor bone. Morris does not teach the current method for at least the reason that Morris does not teach “using a three-dimensional imaging scan,” “measuring parameters . . . from the scan image” or “using a computer assisted device to cut the donor bone.” Dore does not teach the method for at least the reason that Dore teaches modeling body parts while they are in the body, rather than donor bone. Ateshian does not teach the method for at least the reason that Ateshian does not teach processing a bone for implantation – rather Ateshian teaches the manufacture of prosthetic devices.

**Conclusion**

This response is being submitted on or before December 1, 2009, with the required fee for a 3-month extension of time, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

DORSEY & WHITNEY LLP  
**Customer Number 25763**

Date: 11/18/09

By:   
Kenneth E. Levitt, Reg. No. 39,747  
(612) 340-2755